IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

THOMAS PADGETT,

Plaintiff,

vs. CASE NO.: 3:07-cv-00449-HES-HTS

PFIZER INC.;
PHARMACIA CORPORATION, a wholly-owned subsidiary of PFIZER INC.; and
PHARMACIA & UPJOHN COMPANY, LLC, a wholly-owned subsidiary of PHARMACIA CORPORATION,

Defendants.
_____/

DEFENDANTS PFIZER INC., PHARMACIA CORPORATION, AND PHARMACIA & UPJOHN COMPANY LLC'S ANSWER AND DEFENSES AND JURY DEMAND

Defendants Pfizer Inc. (hereinafter "Pfizer"), Pharmacia Corporation (hereinafter "Pharmacia"), Pharmacia & Upjohn Company LLC (incorrectly captioned as "Pharmacia & Upjohn Company, LLC"), (collectively referred to herein as "Defendants") respond to the complaint as follows:

I. PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Bextra®. Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Bextra®.

This preliminary statement is incorporated by reference in its entirety in response to

each and every Paragraph of the Complaint.

II.

ORIGINAL ANSWER

1. Defendants admit that Plaintiff purports to bring this action and seeks damages in excess of $15,000, but deny that there is any legal or factual basis for the purported causes of action and/or damages sought by Plaintiff as a result of Bextra® use.

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this Paragraph of the Complaint except that Defendants are informed and believe that Plaintiff is a citizen of Florida.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of Plaintiff's medical condition or whether he took Bextra®, and therefore deny the same. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the remaining allegations in this Paragraph of the Complaint.

4. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants deny the remaining allegations in this Paragraph of the Complaint.

5. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material hereto" and therefore deny the same, but admit that Pfizer is authorized to do business in Florida. Defendants deny the remaining allegations in this Paragraph of the Complaint.

6. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey.

7. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material hereto" and therefore deny the same, but admit that Pharmacia is a wholly-owned subsidiary of Pfizer.

8. Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold or distributed Bextra®, and deny that it is a proper party in this suit. Defendants deny all remaining allegations in this Paragraph of the Complaint. The response to this Paragraph of the Complaint regarding Pharmacia & Upjohn is incorporated by reference in response to each and every Paragraph of the Complaint referring to Pharmacia & Upjohn and/or Bextra Defendants.

9. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material hereto" and therefore deny the same. Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold or distributed Bextra®, and deny that it is a proper party in this suit. Defendants deny the remaining allegations in this Paragraph of the Complaint.

10. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material hereto" and therefore deny the same. Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold or distributed Bextra®, and deny that it is a proper party in this suit. Defendants deny all remaining allegations in this Paragraph of the Complaint.

11. The allegations in this Paragraph of the Complaint assert a legal conclusion to which no response is required. To the extent a response is required, Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured,

marketed, sold, resold or distributed Bextra®, and deny that it is a proper party in this suit. Defendants deny the remaining allegations in this Paragraph of the Complaint.

12. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material" and therefore deny the same. Defendants admit that during certain periods of time Pfizer and Pharmacia co-promoted and marketed Bextra® throughout the United States, including Florida, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this Paragraph of the Complaint.

13. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

14. Defendants deny that Bextra® is defective and deny the allegations in this Paragraph of the Complaint.

15. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Except as admitted herein, the Defendants deny the allegations in this Paragraph of the Complaint.

16. Defendants admit, and as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary

dysmenorrhea. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Except as admitted herein, Defendants deny the allegations in this Paragraph of the Complaint.

17. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. Should a response be deemed required, Plaintiff fails to provide the proper context for the allegations in this Paragraph of the Complaint and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the allegations in this Paragraph of the Complaint.

18. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. Should a response be deemed required, Plaintiff fails to provide the proper context for the allegations in this Paragraph of the Complaint and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the allegations in this Paragraph of the Complaint.

19. Defendants admit that during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra®, but lack knowledge or information sufficient to form a belief as to the meaning of the phrase "a portion of the extremely lucrative consumer market," and thus deny the same. Defendants deny the remaining allegations in this Paragraph of the Complaint.

20. Defendants admit that Bextra® received FDA approval on November 16, 2001. Defendants further admit, and as indicated in the package insert approved by the

FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant Pfizer admits that, at certain times, it has co-promoted and marketed Bextra® and co-promoted and marketed Celebrex®. Defendants admit that Bextra® and Celebrex® are in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Except as admitted herein, the Defendants deny the allegations in this Paragraph of the Complaint.

21. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this Paragraph of the Complaint.

22. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this Paragraph of the Complaint.

23. Defendants state that the studies referred to in this Paragraph of the Complaint speak for themselves and any attempt to characterize them is denied. Defendants deny the remaining allegations in this Paragraph of the Complaint.

24. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the studies referred to in this Paragraph of the Complaint speak for themselves and any attempt to characterize them is denied. Defendants deny the remaining allegations in this Paragraph of the Complaint.

25. Defendants deny the allegations in this Paragraph of the Complaint.

26. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the allegations in this Paragraph of the Complaint.

27. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the allegations in this Paragraph of the Complaint.

28. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongdoing and deny the allegations in this Paragraph of the Complaint.

29. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the allegations in this paragraph of the Complaint.

30. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in

accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the allegations in this paragraph of the Complaint.

31. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful act, deny that Bextra® caused Plaintiff injury or damages and deny the allegations in this paragraph of the Complaint.

32. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

33. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful act and deny the allegations in this paragraph of the Complaint.

34. Defendants admit that, at certain times, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States for the indications set forth in the FDA-approved

package inserts and as permitted by law. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

35. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that it provided FDA approved prescribing information about Bextra®. Defendants deny any misrepresentations or wrongdoing and deny the allegations in this paragraph of the Complaint.

36. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is defective and deny the remaining allegations in this Paragraph of the Complaint.

37. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

38. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

39. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongdoing and deny the allegations in this Paragraph of the Complaint.

40. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in

accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongdoing or concealment, deny that Bextra® caused Plaintiff injury or damages, and deny the allegations in this Paragraph of the Complaint.

41. Defendants state that the January 2005 letter from the FDA speaks for itself and any attempt to characterize it is denied. Defendants deny the remaining allegations in this Paragraph of the Complaint.

42. Defendants admit that the sale of Bextra® was voluntarily suspended in the United States market as of April 7, 2005. Defendants further state that any statements made by the FDA speak for themselves and any attempt to characterize them is denied. Defendant denies the remaining allegations in this Paragraph of the Complaint, including all subparts.

43. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongdoing or misrepresentation and deny the allegations in this Paragraph of the Complaint.

44. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongdoing or misrepresentation and deny the allegations in this Paragraph of the Complaint.

45. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongdoing or concealment and deny the allegations in this Paragraph of the Complaint.

46. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful act and deny the allegations in this Paragraph of the Complaint.

47. Defendants deny the allegations in this Paragraph of the Complaint.

48. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations whether Plaintiff used Bextra® and therefore deny the same.

Defendants deny any wrongful act, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this Paragraph of the Complaint.

49. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations whether Plaintiff used Bextra® and therefore deny the same. Defendants deny the remaining allegations in this Paragraph of the Complaint.

50. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations whether Plaintiff used Bextra® and therefore deny the same. Defendant states that, in the ordinary case, Bextra® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this Paragraph of the Complaint.

51. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

52. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations whether Plaintiff used Bextra® and therefore deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra is defective, deny that Bextra caused Plaintiff injury or damages, and deny the remaining allegations of this paragraph of the Complaint.

COUNT I

STRICT LIABILITY (as to all Defendants)

With respect to the un-numbered introductory paragraph of Count I, Defendants hereby incorporate by reference their responses to paragraphs 1-52.

53. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® was defective or unreasonably dangerous, and deny the allegations directed toward them in this Paragraph of the Complaint, including all subparts.

54. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

55. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants admit that they have duties as are imposed by law, but deny that they have breached any such duties. Defendants deny the remaining allegations directed toward them in this Paragraph of the Complaint.

56. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and

comported with applicable standards of care and law. Defendants deny the remaining allegations in this Paragraph of the Complaint.

57. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this Paragraph of the Complaint.

58. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants admit that they have duties as are imposed by law, but deny that they have breached any such duties. Defendants deny the remaining allegations directed toward them in this Paragraph of the Complaint.

59. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® was defective and deny the remaining allegations in this Paragraph of the Complaint.

60. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® caused Plaintiff injury or damages, deny that Bextra® is defective, and deny the remaining allegations in this Paragraph of the Complaint.

Defendants deny the allegations set forth in the "Wherefore" paragraph and deny that the plaintiff is entitled to damages or costs.

COUNT II

NEGLIGENCE (as to all Defendants)

With respect to the un-numbered introductory paragraph of Count II, Defendants hereby incorporate by reference their responses to paragraphs 1-52.

61. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants admit that they have duties as are imposed by law, but deny that they have breached any such duties. Defendants deny the remaining allegations in this Paragraph of the Complaint.

62. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint, including all subparts.

63. Defendants state that the potential effects of Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® caused

Plaintiff injury or damages, and deny the remaining allegations in this Paragraph of the Complaint.

64. Defendants deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this Paragraph of the Complaint.

Defendants deny the allegations set forth in the "Wherefore" paragraph and deny that the plaintiff is entitled to damages or costs.

COUNT III

NEGLIGENT MISREPRESENTATION (as to all Defendants)

With respect to the un-numbered introductory paragraph of Count III, Defendants hereby incorporate by reference their responses to paragraphs 1-52.

65. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny the remaining allegations in this Paragraph of the Complaint.

66. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra®

was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this Paragraph of the Complaint.

67. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

68. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

69. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing

information. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this Paragraph of the Complaint.

70. Defendants deny any wrongful conduct and deny the allegations directed toward them in this Paragraph of the Complaint.

71. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

72. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

73. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants admit that they have duties as are imposed by law, but deny that they have breached any such duties. Defendants deny the remaining allegations directed toward them in this Paragraph of the Complaint.

74. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and

comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

75. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

76. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this Paragraph of the Complaint.

Defendants deny the allegations set forth in the "Wherefore" paragraph and deny that the plaintiff is entitled to damages or costs.

COUNT IV

FRAUD (as to all Defendants)

With respect to the un-numbered introductory paragraph of Count IV, the Answering Defendants hereby incorporate by reference their responses to paragraphs 1-52.

77. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

78. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

79. Defendants state that the potential effects of Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate

and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

80. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

81. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

82. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing

information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint, including all subparts.

83. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

84. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

85. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

86. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants admit that they have duties as are imposed by law, but deny that they have breached any such duties. Defendants deny the remaining allegations directed toward them in this Paragraph of the Complaint.

87. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and

comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

88. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

89. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra®, and therefore deny the same. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® caused plaintiff injury or damages, and deny the remaining allegations in this Paragraph of the Complaint.

The Answering Defendants deny the allegations set forth in the "Wherefore" paragraph and deny that the plaintiff is entitled to damages or costs.

Response to Demand for Trial By Jury and Costs

Defendant denies the allegations set forth in the "Demand for Trial by Jury and Costs" Paragraph and denies that the Plaintiff is entitled to an award of attorneys' fees or costs.

III.
GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.
AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant's labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's claims should be diminished in whole or in part in the amount paid to Plaintiff by any party or non-party with whom Plaintiff has settled or may settle.

Sixth Defense

6. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is plead in full bar of any liability as to Defendant.

Seventh Defense

7. Plaintiff's action is barred by the statute of repose.

Eighth Defense

8. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily negligent, actively negligent or otherwise failed to mitigate his damages, and any recovery by Plaintiff should be diminished accordingly.

Ninth Defense

9. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Tenth Defense

10. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Eleventh Defense

11. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Twelfth Defense

12. Defendants affirmatively deny that they violated any duty owed to the Plaintiff.

Thirteenth Defense

13. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided adequate warnings to Plaintiff's treating and prescribing physicians.

Fourteenth Defense

14. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fifteenth Defense

15. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Sixteenth Defense

16. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Seventeenth Defense

17. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Eighteenth Defense

18. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Nineteenth Defense

19. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Twentieth Defense

20. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twenty-first Defense

21. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-second Defense

22. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical products at issue were subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-third Defense

23. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint was at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical products at issue under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable

federal laws, regulations, and rules.

Twenty-sixth Defense

26. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-seventh Defense

27. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-eighth Defense

28. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provide[d] net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Thirtieth Defense

30. Plaintiff's fraud-based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure and/or Rule 1.120 of the Florida Rules of Civil Procedure.

Thirty-first Defense

31. Plaintiff's claims are barred because Bextra® was designed, manufactured, and

marketed in accordance with the state of the art at the time of manufacture per section 768.1257, Florida Statutes.

Thirty-second Defense

32. Bextra® is not defective or unreasonably dangerous, and Defendants are not liable because, at the time of sale or distribution of the Bextra® alleged to have been used by Plaintiff, Defendants had complied with applicable regulations of the federal Food & Drug Administration and are entitled to application of section 768.1256, Florida Statutes.

Thirty-third Defense

33. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fourth Defense

34. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-fifth Defense

35. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-sixth Defense

36. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical product were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the

United States Constitution.

Thirty-seventh Defense

37. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Thirty-eighth Defense

38. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.

Thirty-ninth Defense

39. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Fortieth Defense

40. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purposes for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-first Defense

41. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,

waiver, and/or estoppel.

Forty-second Defense

42. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-third Defense

43. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-fourth Defense

44. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-sixth Defense

46. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product's labeling contained the information that Plaintiff contends should have been provided.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Forty-eighth Defense

48. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Forty-ninth Defense

49. Plaintiff's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiff, or persons or parties whose identities are unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiff's recovery. Thus, Defendants are entitled to have their liability to the Plaintiff, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to the provisions of section 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to sections 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendants' percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendants will be identified in a timely manner consistent with Nash v. Wells Fargo, 678 So. 2d 1262 (Fla. 1996).

Fiftieth Defense

50. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug

Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-first Defense

51. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-second Defense

52. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.
JURY DEMAND

Defendants hereby demand a trial by jury.

VI.
PRAYER

WHEREFORE, Defendants pray that Plaintiff take nothing by his suit, that Defendants be discharged with their costs expended in this matter, and for such other and

further relief to which they may justly be entitled.

s/ Edward W. Gerecke
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Attorneys for Pfizer Inc., Pharmacia Corporation, and Pharmacia & Upjohn Company LLC

CERTIFICATE OF SERVICE

I CERTIFY that on the 1st day of June, 2007, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to C. Todd Alley, talley@alleyingram.com; James D. Clark, jclark@tampatriallawyers.com; Donald Greiwe, dgreiwe@tampatriallawyers.com; and Brenda S. Fulmer, bfulmer@tampatriallawyers.com.

s/ Edward W. Gerecke
Attorney